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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,619	05/01/2006	Heinz Von Der Kammer	2335.0160000/SRL/KPQ	3638
26694	7590	11/24/2008		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	
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			11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,619	Applicant(s) VON DER KAMMER ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner of Record is now **Thaian N. Ton** of Art Unit 1632. The prior restriction requirement, mailed 7/2/08, is withdrawn. A new restriction requirement appears below.

Applicants' Preliminary amendment, filed 5/1/06, has been entered. Claims 1-28 are pending in this application and subject to the following restriction.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-3, 17 and 25, drawn to a method of diagnosing a neurodegenerative disease in a subject and kits for detecting DAX-1 transcripts.

Group II, Claims 1-3, 14, 17, 18 and 25, drawn to methods of diagnosing a neurodegenerative disease in a subject and kits for detecting DAX-1 protein.

Group III, Claims 4-8, 12, 19-23, drawn to transgenic animals comprising DAX-1 and methods of using said animal in a method of developing diagnostics and therapeutics to treat neurodegenerative diseases.

Group IV, Claim 9, drawn to modulators of DAX-1 RNA or proteins.

Group V, Claim 10, 24 drawn to methods of screening for modulators of DAX-1 genes in a cell using *DAX-1 gene*.

Group VI, claims 10 and 24, drawn to methods for screening for modulates in a cell using *DAX-1 RNA*.

Group VII, Claims 10, 15 and 24, drawn to methods of screening for modulators in a cell, using *DAX1- protein*.

Group VIII, claim 11-12, 25, 26 drawn to a method of screening for a modulator of neurodegenerative diseases or related disorders *in vivo*.

Group IX, Claims 13 and 27, drawn to assays for testing a compound to determine the degree of binding to DAX-1.

Group X, Claims 16 and 28 drawn to immunochemical analysis of DAX-1.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of Invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product
- 2) A product and a process of use of said product
- 3) A product, a special process of manufacture of said product, and a process of use of said product
- 4) A process and an apparatus specially designed to carry out said process
- 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant invention.

37 CFR 1.475 (c) states that:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475 (d) states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

The “special technical feature” of Group I determining DAX-1 RNA levels which does not share a technical feature with Group II which is drawn to methods and kits for detecting DAX-1 protein. While both methods are related by being directed to DAX-1, neither uses any of the same components or steps to detect RNA or protein. Furthermore, McCabe et al (US 6,465,627; see figure 12) teach that DAX-1 RNA and protein sequences are known and hence the technical feature of Groups I and II, DAX-1 lacks novelty of inventive step and does not make a contribution over the prior art. Therefore, the technical feature linking the inventions of the groups does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Hence these Groups lack unity of invention.

The technical feature of Group I is considered to be a method of diagnosing a neurodegenerative disease in a subject and kits for detecting DAX-1 transcripts.

The technical feature of Group II is considered to be methods of diagnosing a neurodegenerative disease in a subject and kits for detecting DAX-1 protein.

The technical feature of Group III is considered to be transgenic animals comprising DAX-1 and methods of using said animal in a method of developing diagnostics and therapeutics to treat neurodegenerative diseases.

The technical feature of Group IV is considered to be modulators of DAX-1 RNA or proteins.

The technical feature of Group V is considered to be methods of screening for modulators of DAX-1 genes in a cell using *DAX-1 gene*.

The technical feature of Group VI is considered to be methods for screening for modulates in a cell using *DAX-1 RNA*.

The technical feature of Group VII is considered to be methods of screening for modulators in a cell, using *DAX1- protein*.

The technical feature of Group VIII is considered to be a method of screening for a modulator of neurodegenerative diseases or related disorders *in vivo*.

The technical feature of Group IX is considered to be assays for testing a compound to determine the degree of binding to DAX-1.

The technical feature of Group X is considered to be immunochemical analysis of DAX-1.

Accordingly, Groups are not so linked by the same or a corresponding technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

/Thaia N. Ton/
Primary Examiner, Art Unit 1632